Endo Twinn	510(k) Summary Down Pak			
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	date	23 January 2007		
	author	FV		

510(k) Summary

K070246

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

A. **Name, Address, Phone and Fax number of the Applicant**

EndoTwinn B.V.
Danzigerkade 17
1013 AP Amsterdam
The Netherlands
Telephone: +31 20 486 7571
Fax: +31 20 486 3280

FEB 16 2007

B. **Contact Person**

Frank Verhoeven

C. **Date Prepared**

23 January 2007

D. **Device Name**

Trade Name: Down Pak
Classification Name: Gutta Percha Prosthetic Device, Class 1
Regulation Number and Product Code: 872.3850, EKM
Classification Panel: Dental

E. **Device Description**

The device is a battery-operated dental instrument heater which is designed to provide continuous heat and/or vibration at the tip of a dental instrument. The low frequency vibration stimulates the transformation of gutta percha in a solid mass. The temperature is regulated by the type of tip attached to the handpiece and it automatically maintains a preset temperature for consistent results. The cordless handpiece is easily operated by a single button and can be recharged by placing the handpiece in a charger. The tips are autoclavable and the handpiece can be disinfect with 80% alcohol.

F. **Intended Use**

The intended use of the dental instrument heater – the Down Pak - is to provide continuous heat and/or vibration at the tip of a dental instrument. The Down Pak is designed for processing gutta percha (cutting softening, spreading, compacting) and cutting plastic handles of obturators during a root canal treatment The device may only be operated by dentists and endodontists.

G. **Substantial Equivalence**

The dental instrument heater the Down Pak is a modified version of Endo Twinn and has the same technological characteristics. The modification is to change the plastic material of the tip handle and the user interface.

H. **Device Testing Results**

The Down Pak complies with the requirements of recognized consensus standards

- IEC 60601-1:1988 +A1, A2
- IEC 60601-1-2: 2001
- ISO 14971:2000 + A1
- ISO 10993-5:1999
- ISO 10993-10:2002

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. F.M. Verhoeven
Chief Operational Official
EndoTwinn B.V.
Danzigerkade 17,
Amsterdam, Netherlands 1013 AP

FEB 16 2007

Re: K070246
Trade/Device Name: Down Pak
Regulation Number: 872.3850
Regulation Name: Gutta Percha
Regulatory Class: I
Product Code: EKM
Dated: January 23, 2007
Received: January 25, 2007

Dear Mr. Verhoeven:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070246

Device Name: Down Pak

Indications for Use:

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The device may only be operated by dentists and endodontists.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Lei Muley Sr 1952

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